510(k) Summary of Safety and Effectiveness

JUN 27 2012

C.1 Submitter Information

Submitter:	Contact Name:
Capsule Tech, Inc. 300 Brickstone square, Suite 203 Andover MA 01810 USA	Peter Kelley, Director, Quality Assurance and Regulatory Affairs Capsule Tech, Inc. Phone: 978-482-2309 Fax: 978-482-2980 E-mail: peterk@capsuletech.com

C.2 Date Prepared: December 08, 2011

C.3 Name of Device

C.3.1 Trade Name: DataCaptor™ System

C.3.2 Common Name: Data Collection Software

C.3.3 Classification Name, Class, Product Code and Panel

Classification Name and Regulation Number	Class	Product Code	Panel
Cardiac monitor (including cardiotachometer and rate alarm) - 21 CFR 870.2300	II	MWI	Cardiology

C.4 Substantial Equivalence Claimed to Predicate Device

DataCaptor™ System as cleared via one Traditional 510(k), K013019, and two subsequent Special 510(k)s, K020197, and K032142

C.5 Device Description

The DataCaptor™ System consists of DataCaptor™ Connectivity Software a data acquisition system designed to retrieve and deliver near-real-time data from multiple vendors' bedside medical devices and send it to clinical or hospital information systems in HL7 standard format; Capsule Neuron™ with Docking Station (for high acuity environments) or Mini-Dock (for low acuity environments), a bedside hardware platform for device connectivity, and the DataCaptor™ Terminal Server, a Serial-to-Ethernet concentrator for the medical environment that connects RS-232 equipped bedside medical devices to the hospital network for safe transmission of data to the clinical or hospital information system.

C.6 Intended Use and Indications for Use

The DataCaptor™ System is indicated for use in data collection and clinical information

management either directly or through networks with independent bedside devices. DataCaptor™ is not intended for monitoring purposes, nor is the software intended to control any of the clinical devices (independent bedside devices / information systems) to which it is connected.

C.7 Technology

The modified DataCaptor™ System employs the same technology as the predicate device based on an assessment of relevant Design Control documentation, which is on file at the manufacturer's facility.

C.8 Performance Data

C.8.1 Performance Standards (Section 514 Compliance): no applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device.

C.8.2 Test Summary: design changes in software, hardware and system requirements with respect to the DataCaptor™ System were implemented according to Capsule Tech's Design Control program and are described in detail in this Special 510(k). Design verification and validation activities to pre-determined pass/fail criteria were based on results of risk analysis to confirm system performance, functionality and reliability to be commensurate to the predicate device. The types of design verification and validation activities included software verification and validation of the software changes, environmental and safety testing of the hardware changes, and system validation.

C.9 Conclusion:

The information and data provided in this Special 510(k) Premarket Notification establish that the modified DataCaptor™ System is substantially equivalent to the afore-mentioned predicate device with respect to indications for use/intended use, and technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 27 2012

Capsule Tech, Inc.
c/o Mr. Peter Kelley
Director, Quality Assurance and Regulatory Affairs
300 Brickstone Square, Suite 203
Andover, MA 01810

Re: K113835
Trade/Device Name: DataCaptor™ System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Codes: MWI
Dated: April 30, 2012
Received: May 3, 2012

Dear Mr. Kelley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113835

Appendix B – Statement of Indications for Use

Statement of Indications for Use

510(k) Number (if known): *Unknown*

The DataCaptor™ System is indicated for use in data collection and clinical information management either directly or through networks with independent bedside devices. DataCaptor™ is not intended for monitoring purposes, nor is the software intended to control any of the clinical devices (independent bedside devices / information systems) to which it is connected.

Prescription Use: ___X___ AND/OR Over-the-Counter Use: _____
(21 CFR § 801 Subpart D) (21 CFR §07 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113835